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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/490,609	01/25/2000	Roderick T. Bunch	SO-3170	7385
26648	7590	02/25/2004	EXAMINER	
PHARMACIA CORPORATION GLOBAL PATENT DEPARTMENT POST OFFICE BOX 1027 ST. LOUIS, MO 63006			ZARA, JANE J	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/490,609

Applicant(s)

BUNCH ET AL.

Examiner

Jane Zara

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 25-28 and 31-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25-28 and 31-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This Office action is in response to the communications filed 8-28-03 and 12-3-03.

Claims 25-28, 31-33 are pending in the instant application.

### ***Response to Arguments and Amendments***

#### **Withdrawn Rejections**

Any rejections not repeated in this Office action are hereby withdrawn.

#### **Maintained Rejections**

Claims 25-28, 31-33 are rejected under 35 U.S.C. 112, first paragraph, for the reasons of record set forth in the Office action mailed August 13, 2001 and May 21, 2002, Paper Nos. 12 and 15.

The claims have been amended, and no new arguments have been presented that address the in vivo scope of enablement rejection. The claims are drawn to a method for determining a level or pattern of a carcinogenesis biomarker in a cell, or of measuring the carcinogenicity of a compositions comprising culturing a cell and exposing it to said composition. The claims are drawn to in vivo as well as in vitro conditions. The instant invention is enabled for the methods claimed, wherein the cell being assayed exists in vitro, not in vivo (e.g. inserting the term – in vitro—after “in a cell” in claim 25, line 2; after “cell line” in claim 31, line 3; and after “hepatocyte” in claim 32, line 3 would perhaps be remedial).

The claimed invention is also limited in scope to a method of determining the level or pattern of the nucleic acids expressing the biomarkers of SEQ ID Nos: 280 and 488, not the level or pattern of carcinogenesis protein biomarkers encoded by SEQ ID Nos: 280 and 488, since the instant disclosure teaches the correlation of increased mRNA of SEQ ID Nos: 280 and 488 and not level of expressed proteins or polypeptides. It would require undue experimentation beyond that taught in the instant specification to determine the unambiguous correlation between increases in mRNA expression and increases in polypeptide expression.

*New Rejections*

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 25-28, 31-33 are rejected under 35 U.S.C. 102(e) as being anticipated by Ecker.

Ecker (USPN 6,451,524, Sept. 17, 2002, filed Nov. 25, 1998) teaches methods (including in situ hybridization) for determining a level of pattern of carcinogenesis biomarker in a cell in vitro comprising the detection of the hybridization of a probe that

specifically hybridizes to SEQ ID NO: 280 (a.k.a. regucalcin or senescence marker protein 30), including following exposing the cell harboring the biomarker to a carcinogenic agent (see abstract; col. 1-2; col. 3, line 31-col. 4, line 47; col. 9-10, table 1; col. 13, lines 13-21; claims 1, 6-8).

### ***Allowable Subject Matter***

SEQ ID Nos: 384 and 488 appear free of the prior art of record.

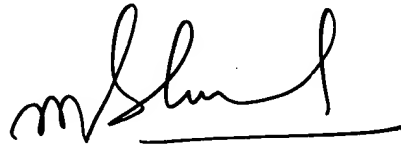
### ***Conclusion***

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is **703-872-9306**. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(571) 272-0765**. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (571) 272-0760. Any inquiry regarding

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this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (571) 272-0564. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'm Shukla', written over a horizontal line.

**RAM R. SHUKLA, PH.D.  
PRIMARY EXAMINER**

**JZ**

2-17-04